DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 16, 2015

Covidien
Timothy Holwick
Sr. Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K143506
Trade/Device Name: Covidien BIS Sensors (BIS Quatro Sensor, BIS Extend, BIS Pediatric Sensor, BIS Bilateral Sensor)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 13, 2015
Received: March 16, 2015

Dear Mr. Holwick,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143506

Device Name
Covidien BIS Sensors (BIS Quatro Sensor, BIS Extend, BIS Pediatric Sensor, BIS Bilateral Sensor)

Indications for Use *(Describe)*
The BIS Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Device Name: The device trade name and common classification names are :

Device Trade Name	Common/Classification Name
BIS Quatro Sensor, BIS Extend, BIS Pediatric Sensor, BIS Bilateral Sensor	*Common Name:* Electrode, Cutaneous Electrode

Address and Registration #: The address and registration number of the manufacturer and sterilization sites for both catheters are:

Manufacturer	Contract Manufacturer
Covidien 6135 Gunbarrel Ave Boulder, CO 80301 FDA Registration #: 2636999	Celestica Electronics PTE LTD. 6 Serangoon North Avenue 5 #05-03/04 Singapore Central Singapore, Singapore 554910 FDA Registration #: 3008202779

Device Class: Cutaneous Electrodes have been classified by the Neurological Devices Panel as Class II, 84 GXY. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Cutaneous Electrodes (21 CFR 882.1320).

Predicate Device Information: Note: Predicate clearances were filed under the technology's previous owner, Aspect Medical Systems Inc., which was thereafter acquired by Covidien. Predicate devices still meet the required element of a Special 510(k) that the proposed changes be based on the company's existing technology as Covidien now owns these technologies.

Aspect Medical Systems BIS Quatro (and Extend) Sensor K093183, concurrence date October 23, 2009
Aspect Medical Systems BIS Bilateral Sensor K062692, concurrence date December 13, 2006.
Aspect Medical Systems BIS Pediatric Sensor K041670, concurrence date July 6, 2004

A reference to multiple predicates is intended to illustrate that the reformulated sensor gel will be used with all four current BIS sensors. No changes have been made to the sensors themselves outside the interaction with the reformulated gel.

Labeling: There are no changes in the labeling or Instructions for Use from the predicate devices.

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Intended Use /Indications for Use	The BIS Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.
Device Description and Comparison	The BIS Sensor, generally speaking with regard to the four variations of the sensor, is a rectangular shaped, pre-gelled array of four zipprep electrodes that is applied to the patient's skin to record electrophysiological signals, such as EEG signals. It is a low impedance, single patient use, disposable electrode sensor designed for application to the frontal/temporal area. The sensor is designed to provide ease of use and electrode placement accuracy. It is in conjunction with Covidien BIS Monitors. The body of the sensor houses three (3) electrodes which are placed on the forehead, and a fourth electrode placed over the temple area. The sensor collects EEG signals from these areas, and the differential signals from the temple and above the eye relative to the center of the forehead are used to calculate the Bispectral Index (BIS) value. The "zipprep" design is constructed using flexible tine disks placed in pockets on a polyethylene basepad. A polyurethane foam disk and hydrogel is placed over the tines. The basepad has a medical grade pressure sensitive adhesive for adhering to the skin. A mylar substrate with conductive silver / silver chloride ink circuit is adhered to the other side of the basepad. The flexible tines, surrounded by hydrogel, are used to part the outermost layer of skin. While the flexible tines part the skin, hydrogel flows around the tines and forms a conductive bridge with the skin. The silver / silver chloride circuit provides signal continuity from each electrode (gel/tine/foam) to the monitor. A polyester insulation is used to restrict electrical contact to the electrode area. The sensor connects to the monitor at a single point (paddle tab) that is low profile and easy to insert and remove. The tab has an electronic smart card memory device that contains identification information (date of manufacture, number of connections, lot number). Each sensor is presented on a silicone liner tray and packed in individual heat-sealed pouches. Twenty-five (25) sealed pouches are packed into a cardboard box.

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Substantial Equivalence	This 510(k) is being submitted for modification to the 510(k) cleared sensors listed in the predicate section above. The gel formulation of the aqueous hydrogel is being changed. This change does not result in any changes to the hazard analysis. A summary of test results, which includes testing to AAMI standard EC12:2000, shelf life testing, and biocompatibility tests for Cytotoxicity, Irritation, and Sensitization is enclosed. All testing results are considered acceptable. Covidien has concluded that the device is substantially equivalent to the predicate devices, with specific regard to the gel, and is safe and effective for its intended use.
Summary of Design Control Activities	Risk analysis was conducted per *ISO 14971: 2007 – Medical devices – Application of risk management to medical devices.* The design verification tests that were performed as a result of this risk analysis are listed in table #1 on the following page. The test methods used are the same as those submitted in the original submission.

Summary of Testing

The following testing was conducted in support of this submission:

- Electrical Testing
- Shelf Life Testing
- Biocompatibility